PHILIPS

sense and simplicity

Scrum / agile and regulatory go together?

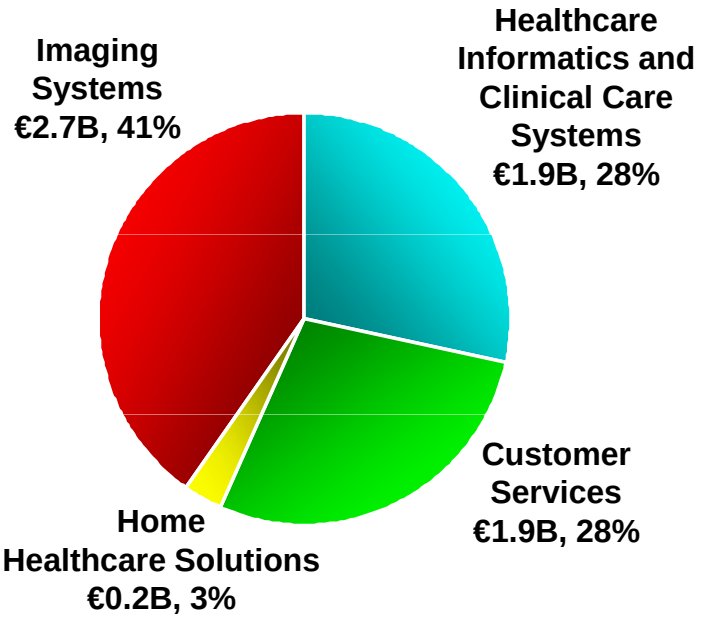
Martin Mermans
Philips Healthcare
November 25

PHILIPS

Contents

- Philips Healthcare
- Standards & Requirements
- Scrum/Agile
- Contradictions?

Philips Healthcare: a global leader for 100 years



2008 sales of €6.9 billion

12% of system sales reinvested in R&D

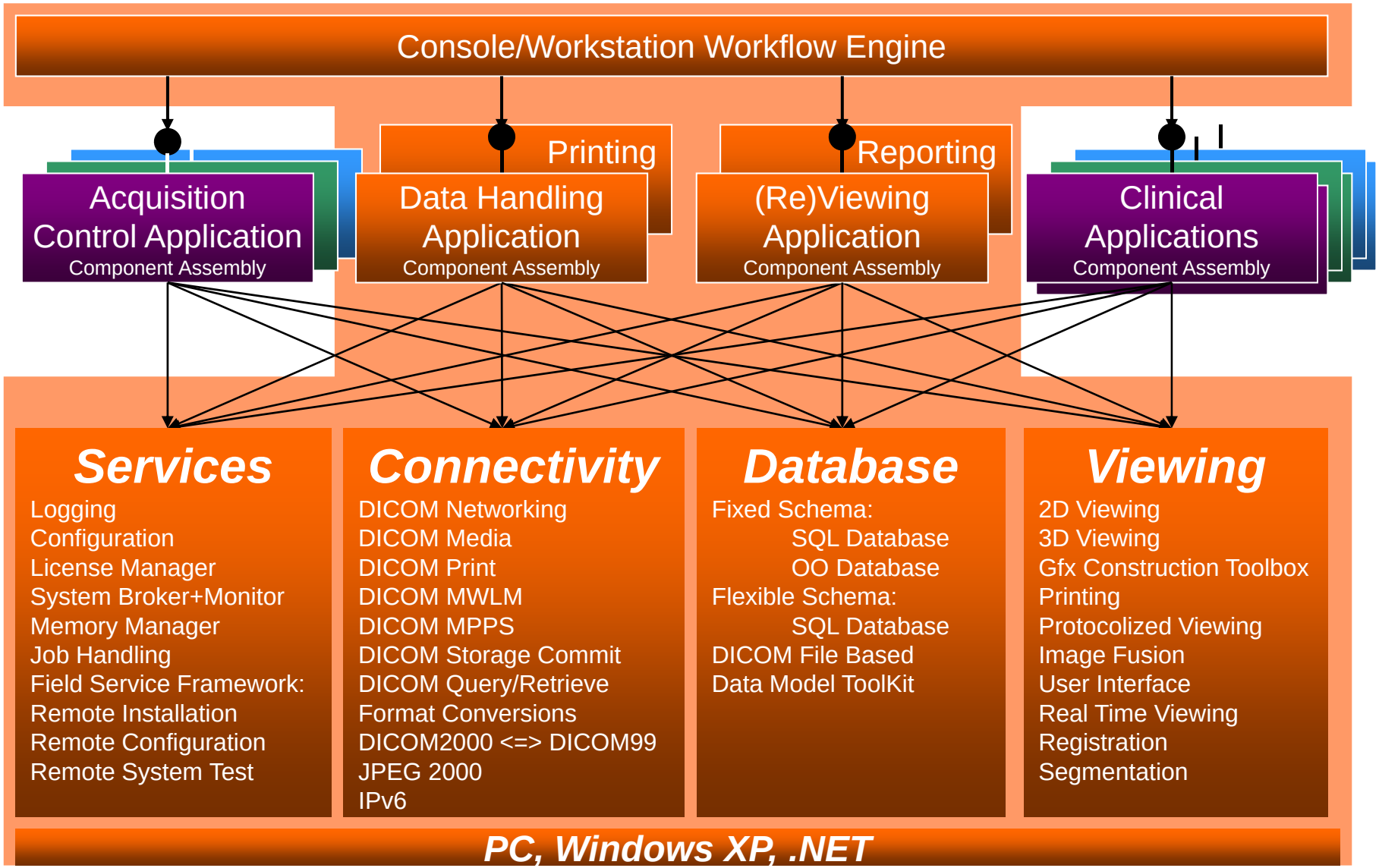
30,000 employees in over 100 countries

Global development and manufacturing sites

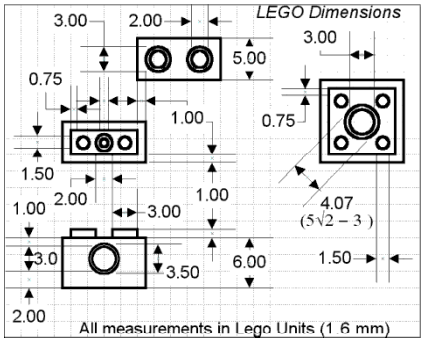
A comprehensive, best-in-class portfolio

General X-ray
Cardio/Vascular X-ray
Ultrasound
Computed Tomography
Magnetic Resonance Imaging
Nuclear Medicine
Positron Emission Tomography
Radiation Therapy Planning
Cardiac and Monitoring Systems
Healthcare IT
Respiration Systems
Customer Services

Component assemblies and the “semi-final”

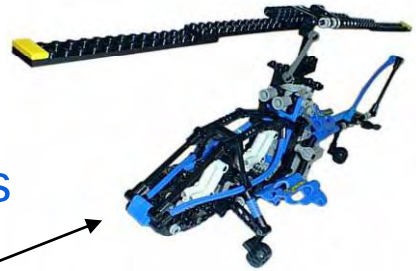


Components….



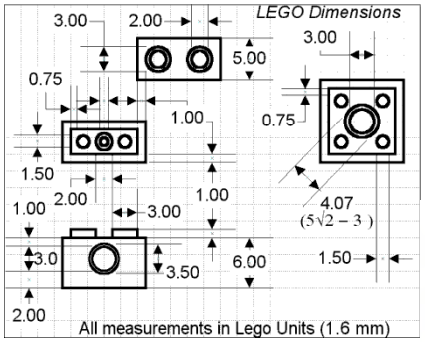
Interface Specs

Software Components



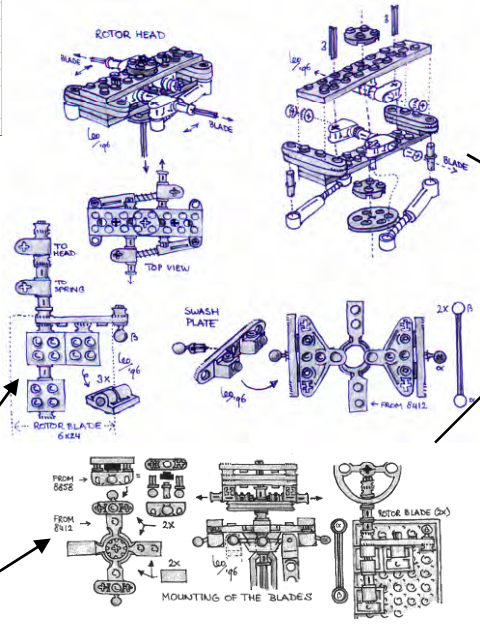
Products

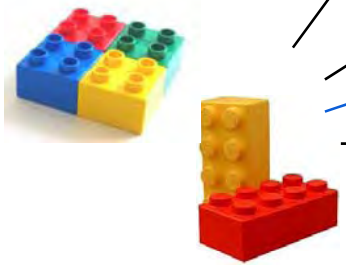
Component assemblies….



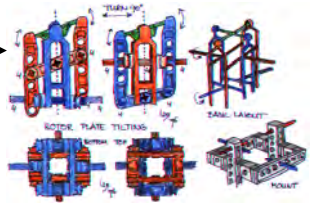
Interface Specs

Standardized Generic Component Assemblies



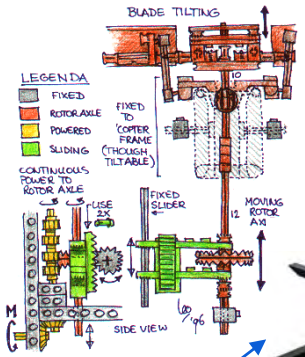


Software Components

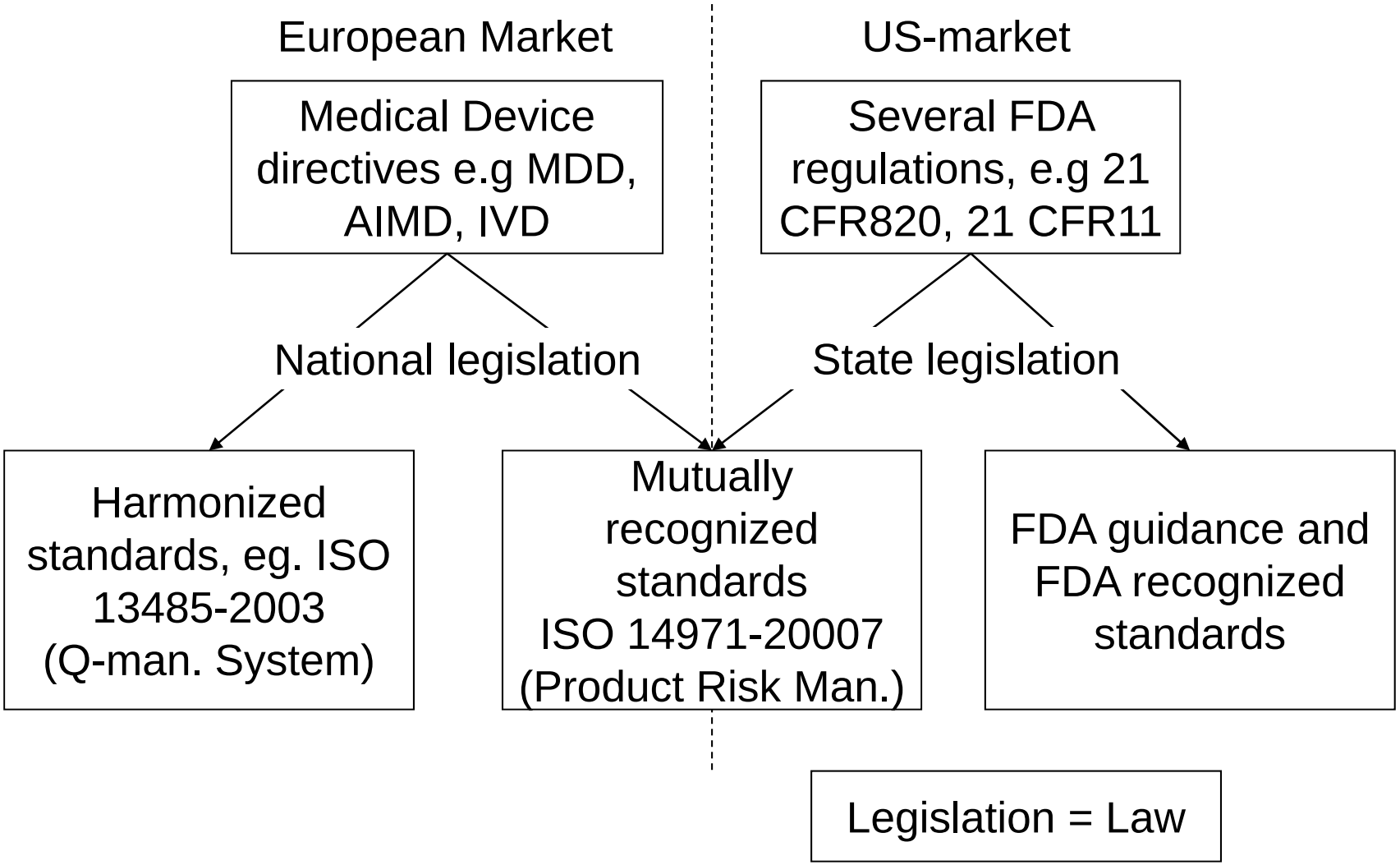


Workspot Semi finals

Standardized System Architectures



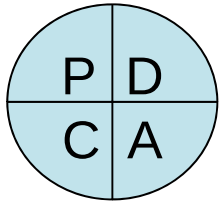
Main regulations & guidance



Standards

- Obligatory
  - Quality System Regulations (FDA 21 CFR 820),
  - The requirements of the EU Medical Device Directive (MDD),
  - Canadian CMDR. (Canadian Medical Device Regulations)
  - ….

- ‘Policy’:
  - CMMi
  - EFQM (Business Excellence)
  - 9001:2000 (if required for business reasons)
  - Specific product related standards: DICOM; HL7; IHE
  - IEEE/EIA Std. 12207.0-1996, Standard for Information Technology – Software life cycle processes
  - IEC 62304 (obligatory?)



Aim of the standards (highlights)

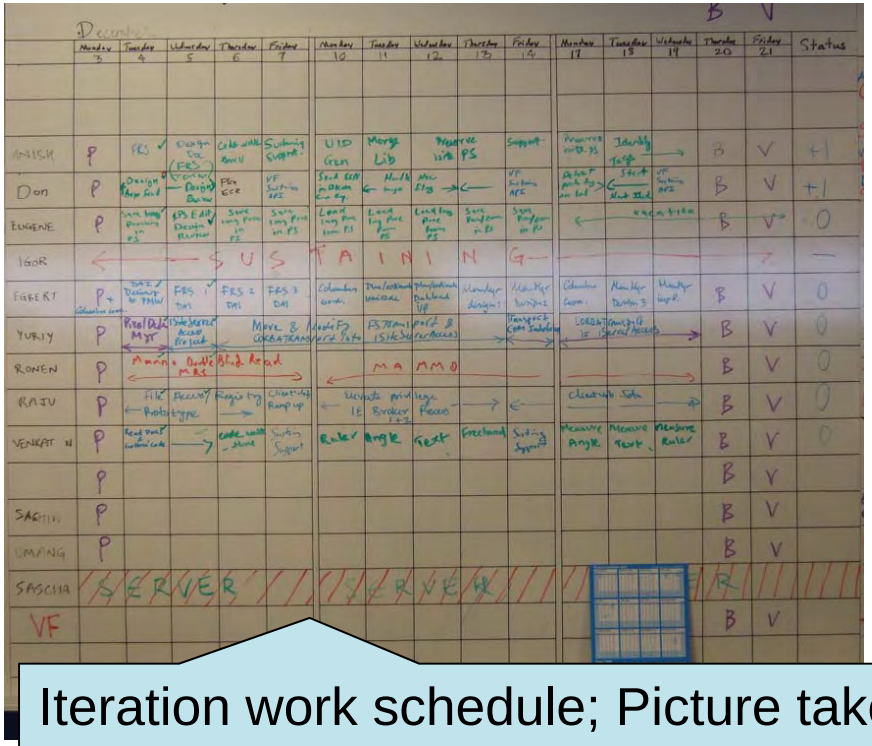
- Product
  - **Safe & Effective** (Given intended use) Pre-market notification
  - Local requirements such as language of UI.
- Process
  - Focus on (product) risk management
  - Sufficient process control to guarantee the above.
    - Plan activities
    - Complaint handling
  - FDA: Not documented is not done
  - CMMi: Predictability (Development Project & Process
  - EFQM: excellence in every process
- Organization
  - FDA & others; CMMi People trained (amongst others on procedures)
  - Management involvement (FDA, CMMi)
  - CAPA / improvement / process management systems

Agile / scrum (we did it our way; multisite)

- Requirements Management
  - Multiple (internal) customers
  - Project scope determined + effort estimates (Project Plan Commitment)
  - Frequent delivery of product for feedback (validation..)
  - Requirements configuration management in Caliber
  - Requirements with safety aspects (from safety risk brainstorm)
- Planning
  - Work breakdown and requirements distribution over teams
  - Each activity broken down, effort estimated and put on scrum board.
  - Requirements delivery distributed over 3 weekly iterations
  - Slack iterations and / or buffer days

PHILIPS

		P = Planned	C = Coded	V = Verified	R=Released			
		Development Phase						
		sprint939	sprint942	sprint945	sprint948	sprint951	Holiday	sprint1003
		37-38-39	40-41-42	43-44-45	46-47-48	49-50-51	52-53	01-02-03
		rev 23798	rev 24374	rev 24761				
REQUI	**Stakeholder Requests**							
	NM							
	STRQ27869 Annotation: Viewer/cell level annotation of color scale, patient orientation		R					
	STRQ27871 Viewing: NM image normalization							
	STRQ27872 Viewing: localization support of data matching (data filtering) in protocol engine							
	STRQ28063 Processing service: backward compatibility support		R					
	STRQ28401 Processing Service: Viewing Operations Support			p	p			
	STRQ28402 Processing Service: Basic Fusion			p	p			
	STRQ28403 Processing Service: 2D/3D Fusion							
	STRQ28404 Processing Service: ROIs and Segmentation							
	STRQ28405 Processing Service: Measurement		R					
	STRQ28406 Processing Service: Dynamic Images/Volumes							
	STRQ28407 Processing Service: Multi-Volumes							
	STRQ30017 Processing Service: Multi-frame image support							
	STRQ30080 Processing Service : Multiple viewers with shared data views should be efficiently supported							
	STRQ30081 Processing Service : Generic resource manager							
	STRQ30810 Viewing : Nearest Neighbor support in orthogonal slab rendering							
	STRQ31014 Viewing : Support cardiac labeling in orientation annotation			R				
	CV							
	STRQ24395 Application Model Service: Basic Requirements		R					
	STRQ24410 Configurable worklist attributes (hospital config). Allow user to configure displayed attributes (user preference)							
	STRQ24568 Almost instanteneous suspend needed on export/print jobs (100 ms) (BeX, GXR-Rank 4)			p	v			
	STRQ24572 Improved connectivity error handling and reporting							
	STRQ24576 Add "no user" logon option							
	STRQ24656 Export a flagged selection via PMW (BeX; GXR-Rank 5)							
	STRQ24780 Smart movie control accessory							
	STRQ25736 Shutters should propagate to other images in the same series or run..							
	STRQ25737 Annotations should propagate to other images in the same series or run (BeX; GXR-Rank 5)							
	STRQ26875 Reconnect to running jobs from datahandler inline progress on restart of PMW							
	STRQ27077 PMW on XP 64bits				p	p		p
	STRQ28181 Add transaction support in database for objects in the same tree							
	STRQ28415 Presentation State Accessory: specify 'preferred' PS			p	p			
	STRQ28454 Auto-save Presentation State			p	p			
	STRQ28476 Generic Cookie mechanism to set user-configurable export settings							
	STRQ28505 Dicom Modality Worklist Support (BeX; GXR-Rank 5)			p	p	v		
	STRQ28537 Application Model Service: Additional Requirements							
	STRQ28538 First step in separation of UI and business logic in VCS for TSM							
	STRQ28610 visual diagnostics in FSF							
	STRQ28611 Console Workflow and MPPS (BeX, GXR-Rank 5)					p		p
	STRQ28612 Application Hosting: Multi-monitor support (BeX)							
	STRQ28613 Application Hosting: multiple patient sessions							
	STRQ28614 Application Hosting: out-of-process portable apps							
	STRQ28804 Pmw should have cold start-up of 20 secs.							
	STRQ30053 Use processing service for export (BeX)							
	STRQ30054 Use processing service for print (BeX)							
	STRQ30057 Save Data for PR (BeX)			p	v			
	STRQ30467 Patient Data Migration: Plug-in mechanism to resolve breaking changes							
	STRQ4616 FSF demo mode							
	PII							
	STRQ24396 Model/viewer split for DataHandler list components		R					
	STRQ24436 Application Portability Overview (document)							
	STRQ24644 Application Portability publish mature interfaces							



Iteration work schedule; Picture taken from CMMi-2 compliant procedure

PHILIPS

Agile / scrum (2)

- Tracking
  - Daily team stand-up’s
  - Remote via web-cam
  - Burn down charts
  - Issue: hour registration
- Configuration Management (of course)
  - Subversion for code (millions LOC)
  - Documents (hundred's) electronically stored
  - Dozen’s of product versions and iterations
  - Tool lists (risk assessed and validated)
- Verification
  - Testers within the team and testing during the lifecycle
  - Verification of iterations

All scrummed

- Product Safe and Effective 👍
  - Product Risk management
  - Extensive verification
  - Documentation and archiving
- Process 👍
  - All activities planned in Scrum
  - Traceability Requirements – Test
  - Early commitment for requirements and content.
- Organization 👍 (not scrum related)
  - Automated procedure training tracking
  - Audits
  - Improvement process (= FDA's CAPA)


PHILIPS